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Docket No.: VAS-5041CIP2

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Dated: August 17, 2006 Name of Person Certifying: Guy Cumberbatch
Printed Name: Guy Cumberbatch (8 pages)

BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shannon) Group Art Unit: 3738
)
Application No.: 09/997,829) Examiner: Brian E. Pellegrino
)
Filing Date: November 29, 2001)
)
For: RADIALLY EXPANDABLE)
TUBULAR STENT GRAFTS)
)

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SUPPLEMENTAL REPLY BRIEF UNDER 37 C.F.R. §41.41

Dear Sir:

This is responsive to the Examiner's (Amended) Answer dated July 6, 2006, which was filed to correct a technical deficiency in the previous Answer dated January 4, 2006 by adding section (8) listing the patents relied upon in the rejection.

The rest of the pending Examiner's Answer essentially duplicates the previous Answer, but also expands the reasons for claim rejections by including the actual text from the Final Office Action dated June 2, 2004 (as opposed to merely incorporating that text by reference).

This Reply Brief supersedes the previous Reply Brief dated February 14, 2006, though no substantive changes have been made. It should be read in conjunction with the Appeal Brief dated November 30, 2004, which presented arguments responsive to the Final Office Action.

Application No.: 09/997,829
Filing Date: November 29, 2001
Supplemental Reply Brief under 37 C.F.R. §41.41 dated August 17, 2006
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Pursuant to MPEP §1208, please note the following:

STATUS OF THE CLAIMS

Claims 103-119 stand rejected.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1) Whether claims 103-105, 107, and 113-117 are not patentable under 35 U.S.C §103(a) as being obvious over U.S. Patent No. 5,700,285 to Myers, et al. in view of U.S. Patent No. 4,131,648 to Choi et al.

2) Whether claim 106 is not patentable under 35 U.S.C §103(a) as being obvious over Myers, et al. in view of Choi et al., and further in view of U.S. Patent No. 6,287, 285 to Michal, et al.

3) Whether claims 108-111 are not patentable under 35 U.S.C §103(a) as being obvious over Myers, et al. in view of Choi et al., and further in view of U.S. Patent No. 6,053,940 to Wijay, et al.

4) Whether claims 108-110, and 112 are not patentable under 35 U.S.C §103(a) as being obvious over Myers, et al. in view of Choi et al., and further in view of U.S. Patent No. 6,117,165 to Becker, et al.

5) Whether claims 118, 119 are not patentable under 35 U.S.C §103(a) as being obvious over Myers, et al. in view of Choi et al., and further in view of U.S. Patent No. 5,749,880 to Banas, et al.

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ARGUMENT

Responsive to the Examiner's Answers, Applicant wishes to reply by emphasizing the lack of motivation to combine the two primary references. The main issue on appeal is:

1) Whether claims 103-105, 107, and 113-117 are not patentable under 35 U.S.C §103(a) as being obvious over U.S. Patent No. 5,700,285 to Myers, et al. ("Myers") in view of U.S. Patent No. 4,131,648 to Choi et al. ("Choi").

Applicant again respectfully submits that Myers in combination with Choi does not render the pending claims obvious to one of ordinary skill in the art, primarily because the Examiner has not established a *prima facie* case of obviousness.

Sole independent claim 103 is reprinted below:

103. (Previously presented) An implantable drug eluting device that has a compressed undeployed diameter and an expanded deployed diameter, the device comprising:

a radially expandable stent comprising a generally cylindrical wall surface and having a hollow bore extending longitudinally therethrough, wherein the generally cylindrical wall surface comprises a plurality of lateral openings in the wall surface;

a coating comprising a polymer and a therapeutic substance disposed on the wall surface of the stent; and

a tubular outer layer comprising expanded, sintered PTFE tape wound about the outer surface of said stent.

Myers, et al. discloses a tubular intraluminal graft comprising a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall having a multiplicity of openings through the wall, and a tubular covering of porous expanded PTFE film affixed to the stent. There is absolutely no mention of incorporating a therapeutic substance (i.e., a drug) into the intraluminal graft.

Choi discloses generally a polymer formulation in which a "beneficial agent" is incorporated. The polymers exhibit a controlled degree of the erosion in an aqueous environment and thus can be used for making devices and coatings for releasing a beneficial agent as the polymers erode. However, Choi offers no suggestion that a stent or graft can be coated with the polymers disclosed. Importantly, various examples in Choi are given, none of which include a stent or graft, as has been illustrated in the Appeal Brief by reiteration of the examples of Choi:

FIG. 3 - exemplary square shape

FIG. 4 - multilayered structure

FIG. 5 - two layers of different polymers having different bioerosion rates

FIG. 6 - bioerodible polymer having a multiplicity of microcapsules

FIG. 7 - a support base layer formed of a breathable impervious material, with a bioerodible solid polymer containing a drug fixed thereto...useful for administering drug to the skin, mucosa or an exposed wound.

FIG. 8 a depot implant comprised of a pair of layers and a single layer sandwiched therebetween...after an operation is completed and the patient regains consciousness, an implant containing an analgesic can be implanted into the body to ease pain as it bioerodes

FIGS. 9 and 10 a device having a cylindrical shape and a passageway extended through the center made of a bioerodible polymer for releasing drug within a vagina. The passageway manipulates the amount of drug released by increasing the surface exposed to the fluid of the environment of use. FIG. 10 illustrates a device for insertion into the natural cavities such as the anus 25.

FIGS. 11a and 11b - a device for placement in a human eye including an ocular insert consisting of a bioerodible polymer.

FIG. 12 - a device for releasing a drug within a uterus 36 having a round tube shaped body made of bioerodible polymer that contains a drug.

While the Examiner may be familiar with the pertinent legal standards for obviousness, the Examiner has misapplied these standards in the instant case. The Federal Circuit cases cited by the Examiner in support of this position, in fact, contradict his position. Thus, the Examiner cites the following cases: In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000) (Court reversed obviousness rejection involving technologically simple concept because there was no finding as to the principle or specific understanding within the knowledge of a skilled artisan that would have motivated the skilled artisan to make the claimed invention); and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992) (The court found there was no suggestion to combine these references to arrive at the claimed invention). In each of these cases, the Federal Circuit reversed the Board of Appeals and found no basis to combine the references at issue; i.e., no *prima facie* case was found.

The standard for combining references has been stated in slightly varying ways, though the following passage from In re Dembiczak (copy attached) is a comprehensive example.

> We have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, see Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), Para- Ordinance Mfg. v. SGS Imports Intern., Inc., 73 F.3d 1085, 1088, 37 USPQ2d 1237, 1240 (Fed. Cir. 1995), although "the suggestion more often comes from the teachings of the pertinent references," Rouffet, 149 F.3d at 1355, 47 USPQ2d at 1456. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be ***clear and particular***. See, e.g., C.R. Bard, 157 F.3d at 1352, 48 USPQ2d at 1232. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence." In re Dembiczak, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618 (Fed. Cir. 1999).

It is interesting that the Examiner quotes the "clear and particular" phrase from In re Dembiczak when, in fact, the court's language completely undermines the Examiner's argument in the instant case. Far from offering any actual evidence "of a suggestion, teaching, or motivation

to combine" the cited references, the Examiner ignores the Court's prohibition against using "broad conclusory statements regarding the teaching of multiple references, [that] standing alone, are not 'evidence.'"

For a section 103 obviousness combination, the Federal Circuit recognizes that there may be a) explicit evidence within the references themselves, or b) implicit evidence from "the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved." In the present case the Examiner has not identified any explicit suggestion in Choi or Myers to combine the two teachings. Instead, the Examiner admittedly relies on the implicit form of evidence to make the combination.

Specifically, at pp. 6-7 of the Answer, the Examiner states that

> stent-grafts are used in vessels, which permit the flow of fluid, whether it is blood, urine or even bile. Choi teaches that the polymer coatings containing drugs are used in aqueous or 'fluid' environments (Col. 28, lines 61-68) and that the device the polymer is used with can permit the drugs to be transported across a vessel, col. 29, lines 24-29. It is well known to one of ordinary skill in the art that blood vessels, ureter, urethra or bile ducts all carry fluid that would be considered an aqueous environment and that stent-grafts are often used to hold open and support these vessels when they are blocked, clogged, or have a reduced flow rate. Someone of ordinary skill in the art would also know what a coating is and would look to the coating art to provide a delivery vehicle for drugs. Therefore, the motivation can be implicit from the prior art as a whole, rather than expressly stated in the references and Choi clearly implies blood vessels can be one possible treatment site in which a device, i.e. stent-graft is used to correct for failure of blood flow.
>
> ...In conclusion, to provide a *drug* delivery device is an obvious expedient to one of ordinary skill in the art and one of ordinary skill in the art would look for ways to accomplish that. Using a drug containing coating clearly accomplishes that objective.

By the Examiner's own admission, all that Choi discloses is a drug containing coating and the implication of a blood vessel as a treatment site. From there the Examiner conveniently uses "an obvious expedient", whatever that may be, to make the imaginary leap of putting Choi's coating on Myers' graft. Using the Examiners's logic, "an obvious expedient" can be fabricated

to make every invention obvious. Choi does not once mention either the term "stent" or the term "graft," and, therefore, does not suggest coating a wall surface of a cylindrical stent having a plurality of lateral openings with a bio-erodible polymer. Choi merely teaches that the erodible polymers disclosed therein "can be made into" implantable devices (see Choi, col. 28, ll. 15-17). This is too general for the "clear and particular" standard required by the Federal Circuit.

Moreover, claim 103 also specifies a sintered PTFE tape wound around the outer surface of the stent to form a tubular outer layer. The Examiner's general proposition that because Choi teaches a bio-erodible polymer, one of skill in the art would be motivated to coat the stent of Myers around which a PTFE tape is then wound is nothing but a hindsight reconstruction of the claim. It is important to recall the Federal Circuit's admonition in In re Dembiczak:

> Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, the Board fell into the hindsight trap.

There is simply no clear, particular suggestion or motivation in the prior art, explicitly or implicitly, to make the specific combination of a stent, a polymer-therapeutic substance coating on the stent and a PTFE tape wrapped on the outside of the stent as recited in the pending claims.

To say that Choi's general teaching of a bio-erodable polymer would be combined by one of skill in the art with the stent of Myers, a reference that does not mention the need for therapeutic drug incorporation, is without the requisite basis. Indeed, the Examiner's view of the applicability of Choi to implants in general is without boundary, because the same logic could be used to combine Choi with stents other than that disclosed in Myers. This appears to be a classic case of taking "the inventor's disclosure as a blueprint."

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For the foregoing reasons, the Examiner's rejection should be overturned and the pending claims allowed to issue.

Respectfully submitted,

Date: August 17, 2006

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